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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,761	02/07/2005	Bernard Charles Sherman	PT-2099001	1380

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EXAMINER	
PALENIK, JEFFREY T	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
10/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,761	SHERMAN, BERNARD CHARLES	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 7-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

The Examiner thanks the Applicants for their timely reply filed on 7 April 2008, in the matter of 10/523,761. A response to the remarks and amendments are herein presented under 37 CFR § 1.113.

The Examiner acknowledges that claim 1 has been amended further narrowing the scope of the granule composition. Claims 3 and 4 have been amended in their dependencies. Claim 3 was further amended in view of the specification (see page 3, lines 18-20).

Claims 2 and 6 have been cancelled.

New claims 7-11 have been added.

The Examiner acknowledges that no new matter has been added as a result of any amendments or additions.

Claims 1, 3-5 and 7-11 are now pending.

Information Disclosure Statement

No new Information Disclosure Statements have been submitted for consideration.

Withdrawn Objections/Rejections

Objection to Specification

Applicant's amendment to the Abstract of the Invention, placing on a separate page/document renders the objection moot. Thus, said objection has been **withdrawn**.

Rejection under 35 USC 102

Applicant's amendments to claim 1 render the rejection of claims 1, 3 and 4 under 35 USC 102 over Krishnamurthy et al. (USPN 6,419,960) moot. Thus, said rejection has been **withdrawn**.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 7 November 2007:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devane et al. (U.S. Patent 6,228,398).

Devane et al. teaches a multiparticulate modified release composition that delivers an active ingredient in a bimodal manner (Abstract). Methylphenidate HCl is clearly the main active agent that is taught (claim 13) and clearly contemplated as the only agent taught (see Examples). Example 1 teaches formulations of methylphenidate hydrochloride mixed with different functionally equivalent release coatings such as polyvinyl pyrrolidone and Eudragit®. Polyvinyl acetate phthalate is clearly taught as a coating to be used with the active agent methylphenidate HCl. However, Devane does not teach the specific ratios claimed.

In the very least, polyvinyl acetate phthalate is taught as another coating material that is a functional equivalent to the aforementioned coating materials in that it also modifies the release of the active ingredient (column 8, line 62 to column 9, line 1). One of ordinary skill in the art at the time of the invention would therefore, have been motivated to substitute polyvinyl acetate phthalate as a functionally equivalent coating material in the composition with a reasonable expectation that bimodal release of the active agent (e.g. methylphenidate) would be retained and since its use is clearly conceived of as a coating on the only active agent contemplated in the invention, namely Methylphenidate HCl. Furthermore, the adjustment of particular conventional working conditions (e.g., determining result effective amounts of the ingredients beneficially taught by the cited references, especially within the broad ratios instantly claimed), as well as using a functionally equivalent coating material, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Response to Arguments

Applicant's arguments with regard to the rejection of clams 1, 3 and 4 under 103 over Devane have been fully considered but they are not persuasive.

Applicant alleges that the invention practiced by Devane et al. (USPN 6,228,398) differs from the amended claims since it teaches not only two types of granules in the composition in addition to teaching the granules as being surface-coated. Applicant further alleges that the claimed granules differ from those which are taught by Devane since Devane teaches a core seed and the instant claims do not recite said core. Lastly, Applicant that the polymer/drug ratio is out of the limits of the claimed ratio.

In response, the Examiner respectfully maintains, particularly in view of Applicant's amendments, that Devane continues to read on the rejected claims 1, 3 and 4. Claim 1 of Devane is directed to a multiparticulate modified release composition containing at least one active ingredient and having a first component, the combination of which comprises a first population of active ingredient containing particles. The claim further teaches that the composition comprises at least one subsequent component, wherein each subsequent component comprises a subsequent population of active ingredient-containing particles, wherein the active ingredient in the first and subsequent components may be the same. The subsequent population of active ingredient containing particles further comprises a modified release matrix. Claim 6 teaches that the active agent in the first and subsequent populations is the same. Claim 11 teaches methylphenidate as the active ingredient. Enteric polymer compounds used to create the instantly claimed modified release matrix such as polyvinyl acetate phthalate (PVAP), microcrystalline cellulose (MC), polyvinylpyrrolidone or povidone or PVP, and

polyalkylmethacrylates such as Eudragit®, are taught (col. 10, lines 4-14). Example 2 teaches different formulations of methylphenidate HCl combined with enteric polymers wherein the resulting dosage ratio between the two release populations is 4:1 (i.e. microcrystalline cellulose:methylphenidate). Given that PVAP, povidone, Eudragit® and MC and are taught as functionally equivalent enteric polymers, it would have been well within the purview of the skilled artisan to form the active-loaded matrix populations exclusively using PVAP as the enteric polymer and methylphenidate as the active. Thus, two granular populations contain the same active agent and are contained by the same enteric polymer, thereby creating a single population of methylphenidate and PVAP. The substitution of PVAP for the functionally equivalent enteric polymers of Example 2 not only teaches the claimed ratio as being greater than 4, but also that it is adjustable, given that multiple polymers are used which are functionally equivalent to PVAP.

Devane does teach using a non-pareil seed as a foundation on which controlled release compositions may be formed, as stated by Applicant (see also Example 1). However, the invention to Devane still reads on the instant claim 1 despite amending and narrowing the scope of the formulation mixture (i.e. "consisting essentially of" the drug and polymer). Per MPEP §2111.03, the transitional term "consisting essentially of" limits the scope of a claim to the specified materials "and those that do not materially affect the basic and novel characteristics" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). Since the "seed", which is taught, is a non-pareil seed (e.g. inert sugar seed), it is considered by the Examiner to non-reactive and thus contributing nothing to the novelty of the claimed compound.

For these reasons, Applicant's arguments are found unpersuasive. Said rejection is therefore maintained.

New Rejections

Consideration on the merits has been given to Applicant's amended and newly added claims, submitted in the response dated 7 April 2008. The following new rejections are presented:

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and **generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5 and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships missing particularly from claims 1 and 10 are: what the instantly claimed composition further comprises if not a coating over the "uncoated particles" (i.e. what else beyond the drug and polymer are within the composition).

The remaining claims are rejected as being dependent from the rejected independent claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-5 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devane et al. (USPN 6,228,398).

The instant claims are directed to a composition comprising a single population of uncoated particles of a homogenous mixture, which consists essentially of a water-soluble drug and an enteric polymer, wherein the ratio of polymer to drug ranges from greater than 4 to less than 100. Claims 3 and 4 recite narrower ranges for the ratio. Claims 5 and 7 recite size limitations to the particles formed wherein the particles should pass through a #8 mesh screen, but not through a #16 mesh screen. Per Sigma-Aldrich, the #8 mesh size corresponds to a size of 2.38 mm and the #16 mesh size corresponds to 1.19 mm (see *Particle size - sieve mesh conversion chart*). Therefore, the limitation of claim 5 is interpreted as reciting particles ranging in size from 1.19-2.38 mm. With regard to the release limitation, recited in claim 7, until some material difference in the properties of the composition is demonstrated, said limitation is considered by the Examiner to be directed toward the composition which is instantly claimed. Given that the limitation recited in claim 7 is functional, the claim is considered by the Examiner as reciting the same subject matter as claim 5. Methylphenidate is recited as the water-soluble drug and polyvinyl acetate phthalate (PVAP) is recited as the enteric polymer (claims 8 and 9). Newly added claim 10 recites the same subject matter as claims 1 and 5, further specifying methylphenidate as the water-soluble drug and reciting a drug/polymer ratio of greater than 10 to less than 50. Claim 11 recites PVAP as the enteric polymer.

The teachings of Devane are discussed above where they apply to the instant claims 1, 3 and 4, particularly in the *Response to Arguments* section. Devane further teaches multiparticulate modified release compositions containing methylphenidate wherein said composition is applied to non-pareil seeds, which range in size up to 0.85 mm.

Devane does not expressly teach the claimed size range for the prepared granules (i.e. between #8 and #16 mesh), as instantly claimed by Applicant. Nor does Devane expressly teach methylphenidate as being exclusively mixed with PVAP to form the claimed granules.

As discussed above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising populations of particles consisting of the water-soluble drug methylphenidate and a release matrix polymer such as PVAP, as suggested by Devane, modify the levels or ratios of the ingredients, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Devane teaches, as discussed above, that the PVAP is a functionally equivalent matrix polymer to those which are expressly taught, either in the claims or in the Examples. Furthermore, in view of the Examples as well as the teachings of claims 1 and 6, an artisan of ordinary skill would have been motivated to create a first population of particles consisting of one ratio of methylphenidate to PVAP and then create a second population consisting of the same components, but mixed in a different ratio. Such a composition would not only consist of the instantly claimed components, but also possess differing polymer/active ratios, which would, in effect, demonstrate distinct release rates, thereby producing the instantly claimed bimodal release.

Regarding the polymer/drug ratio and the sized granules, since the values and formats of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. For example, as taught in Example 1, the release characteristics of the

modified release component are taught as being variable simply by changing the composition and thickness of the coating applied to the non-pareil seed. Thus, it would have been customary for an artisan of ordinary skill, to vary the amounts of methylphenidate and polymer within the composition, as well as to adjust the thickness of the composition which is applied to the seed, in order to achieve the desired component ratio and bimodal release pattern. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

All claims have been rejected; no claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615